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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,393	01/26/2004	Richard L. Veech	604-707	4584

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EXAMINER	
THOMAS, TIMOTHY P	
ART UNIT	**PAPER NUMBER**
1609	

MAIL DATE	DELIVERY MODE
06/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,393	VEECH, RICHARD L.	
	Examiner	Art Unit	
	Timothy P. Thomas	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32 and 33* is/are rejected.

7)☒ Claim(s) *32 and 33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/26/04 & 5/9/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of

1) restriction requirement: the subject matter of Group I, claims 1, 2, 4-18, and 28; and

2) species elections: C_8 fatty acid triglyceride and memory loss associated with aging,

in the reply filed on 5/9/2007 is acknowledged. Since the restriction and election requirement was not traversed, the requirement is deemed proper and made FINAL.

Status of Application

2. The amendments to the claims, filed 5/9/2007, are acknowledged. Claims 1-31 have been cancelled and new claims 32-33 have been added.

Priority

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120/365 and119(e) as follows:

4. This application is claiming the benefit of provisional application No. 60/040,858 under 35 U.S.C. 119(e). However, this application was not filed within twelve months from the filing date of the provisional application, and there is no indication of an intermediate nonprovisional application that is directly claiming the benefit of the

provisional application and filed within 12 months of the filing date of the provisional application.

Note: If the day that is 12 months after the filing date of the provisional application falls on a Saturday, Sunday, or Federal holiday within the District of Columbia, the nonprovisional application claiming the benefit of the provisional application may be filed on the next succeeding business day.

Applicant is required to delete the reference to the prior-filed provisional application from the first sentence(s) of the specification or the application data sheet, depending on where the reference was originally submitted, unless applicant can establish that this application, or an intermediate nonprovisional application, was filed within 12 months of the filing date of the provisional application.

5. It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/843694 (from which 10/153873 may be a CON); which is a CON of 09/397100, which is a CON of the claimed priority document, PCT/US98/05072; filed 4/30/2001; 9/16/1999; and 3/17/1998, respectively. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing

date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference

was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

The preliminary amendment to the specification, and the declaration, both filed 1/26/2007, make reference to the PCT application, PCT/US98/05072, filed 3/17/1998, incorrectly dated 3/17/1997 on the declaration, but the required intervening priority applications have not been identified. Therefore, the claimed priority date of 3/17/1997 is not allowed.

The priority date, established for the purpose of examination on the merits and the determination of prior art dates, is 05/24/2002, the filing date of application # 10/153,873.

Information Disclosure Statement

6. The information disclosure statement filed 1/26/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

7. Claims 32-33 are objected to because of the following informalities: The word "define", in the 5th line of Claim 32 appears to be misspelled. Suggestions are to correct the spelling to "defined", or to change the grammar of the sentence. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 32-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of the connecting term, "such as" in line 4 of Claim 32 renders two possible meanings for the claim. The first would be where the elevation of the patient's blood levels of ketone bodies occurs because of administration of one or more of the compounds claimed in the previous phrase, presumably due to metabolism of the administered compound(s); the second meaning would be where the phrase "to elevate the patients blood levels of ketone bodies" is somehow construed to be an example of administering a therapeutically effective amount of the compound(s), and not a result of administering. In the second case, the use of the phrase "such as" is not appropriate. Therefore, the use of this phrase renders the claim and the claim dependent on it indefinite.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 32-33 are rejected under 35 U.S.C. 102(a & e) as being anticipated by Martin et al. (US 6,380,244 B2).

Martin teaches all of the components of the claims: increasing ketone body levels in the blood of mammals by oral administration of linear or cyclic oligomers and/or derivatives of 3-hydroxyacids, preferably 3-hydroxybutyrate, alone, or in combination with acetoacetate (abstract); D-ß-hydroxybutyrate is taught (column 3, line 21); as are free fatty acids and triglycerides (column 7, line 25); treatment of a variety of neurodegenerative diseases using these compounds, including Alzheimer's disease, vascular dementia, senile dementia of Lewis body type, dementia of Parkinsonism with frontal atrophy (an inherent component of these conditions is memory loss associated with aging) (column 8, lines 28-48); these compounds are effective, at least in part, because using elevated levels of ketone bodies can improve nerve cell function and

growth (column 8, lines 28-48); amounts administered result in blood levels typically in the range of 7.5 mM (column 8, lines 28-48).

12. Claims 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Veech (US 6,207,856 B1).

Veech has previously disclosed the instant invention; with all of the components of the instant claims: administration of compositions comprising ketone bodies and/or their metabolic precursors that retard or prevent brain damage in memory associated brain areas such as found in Alzheimer's and similar conditions (abstract); treatment of Alzheimer's disease and other types of dementia are taught, including impairment of recent memory leading to dementia and death (memory loss associated with aging) (column2, line 61-column 3, line 57; column 20, lines 4-13); utilizing D-ß-hydroxybutyrate and acetoacetate are taught (i.e., column 7, lines 34-40); as are oral or parenteral administration of free fatty acids or triglycerides, which increase blood ketone levels to 2 mM or 5 mM (column 9, line 67-column 10, line 65); the treatment for neurodegeneration, such as Alzheimer's and Parkonsonianism, preferably elevates blood levels of ketone bodies to 0.5-20 mM (column 20, lines 32-35).

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 32-33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 5-7, 19 of U.S. Patent No. 6,323,237. Although the conflicting claims are not identical, they are not patentably distinct from each other because all of the elements of these claims are present in both sets of claims. The claims in the patent include a larger group of disorders. In view of the specification, the predominant condition disclosed is Alzheimer's disease, for which clinical diagnosis depends on discovery of the symptoms of memory loss in older patients; therefore it would be obvious to one skilled in the art to utilize this method of treatment for patients with memory loss associated with aging.

15. Claims 32-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5-9 of copending Applications No. 09/843694, 10/153873, 10/408667; claims 17, 33, 44, 45 of copending Application No. 10/559258; and claims 1, 4, 6, 7, 8, 11 of copending Applications No. 09/799124, 10/394644, 10/734586. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The first set of applications contains identical claims to the previous version of claims in the instant application. The amended instant claims are nearly identical to the identified claims, except the copending claims include a larger group of disorders and compounds. In view of the specification, the predominant condition disclosed is Alzheimer's disease, for which clinical diagnosis depends on discovery of the symptoms of memory loss in older patients, examples specifically utilize compounds of the instant claims; therefore it would be obvious to one skilled in the art to utilize this method of treatment for patients with memory loss associated with aging, and to select the claimed compounds.

The second set of an application utilizes administration of an oligomer to raise blood levels of ketone bodies in order to treat a group of conditions, which include Alzheimer's disease, Parkinson's disease, Pick's disease and amyotrophic lateral sclerosis. In view of the specification, such oligomers are disclosed as "metabolic precursors" of the instant claimed compounds; the predominant condition disclosed is Alzheimer's disease, for which clinical diagnosis depends on discovery of the symptoms of memory loss in older patients, examples specifically utilize compounds of the instant claims; therefore it would be obvious to the skilled artisan to utilize this method of treatment for patients with memory loss associated with aging, and to utilize the oligomers in the treatment.

The third set of applications utilize cyclic oligomers of 3-hydroxybutyrate and their use in treatment of a group of diseases, including Alzheimer's disease and Parkinsonism, among others and as a nerve stimulant, where serious clinical

consequences exist. In view of the specification, such cyclic oligomers are disclosed as "metabolic precursors" of the instant claimed compounds; the predominant condition disclosed is Alzheimer's disease, and the involvement of neuron decay and death in that disease, for which clinical diagnosis depends on discovery of the symptoms of memory loss in older patients, examples specifically utilize compounds of the instant claims; therefore it would be obvious to the skilled artisan to utilize this method of treatment for patients with memory loss associated with aging, and to utilize the cyclic oligomers in the treatment.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

16. Both of the pending claims, 32-33, are objected to and rejected. Claims 1-31 have been cancelled.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy P. Thomas whose telephone number is (703) 272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Cecilia Tsang or Janet Andres can be reached on (571) 272-0562 or (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TPT/
Timothy P. Thomas, Ph.D.
Patent Examiner

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER